



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 106

[Docket No. FDA-2014-D-0044]

Exempt Infant Formula Production: Current Good Manufacturing Practices, Quality Control Procedures, Conduct of Audits, and Records and Reports; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of availability.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a guidance for industry entitled “Exempt Infant Formula Production: Current Good Manufacturing Practices (CGMPs), Quality Control Procedures, Conduct of Audits, and Records and Reports.” The guidance describes our current thinking on the manufacturing of exempt infant formula in relation to the requirements for CGMPs, quality control procedures, conduct of audits, and records and reports that apply to non-exempt infant formulas.

DATES: Submit either electronic or written comments on FDA guidances at any time.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your

comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <http://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2014-D-0044 for the "Exempt Infant Formula Production: Current Good Manufacturing Practices (CGMPs), Quality Control Procedures, Conduct of Audits, and Records and Reports." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions,"

publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at:

<http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the

prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of the guidance to the Office of Nutrition and Food Labeling, Center for Food Safety and Applied Nutrition (HFS-850), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your request. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Carrie L. Assar, Center for Food Safety and Applied Nutrition (HFS-850), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-1453.

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of a guidance for industry entitled “Exempt Infant Formula Production: Current Good Manufacturing Practices (CGMPs), Quality Control Procedures, Conduct of Audits, and Records and Reports.” Section 412(h)(1) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 350a(h)(1)) exempts an infant formula that is represented and labeled for use by an infant with an inborn error of metabolism, low birth weight, or who otherwise has an unusual medical or dietary problem from the requirements of sections 412(a), (b), and (c) of the FD&C Act. These formulas are customarily referred to as “exempt infant formulas.” The guidance is intended to describe the significance of the regulations in 21 CFR part 106 for the production of exempt infant formulas. A final rule amending part 106 was published in the Federal Register on June 10, 2014 (79 FR 33057).

In the Federal Register of February 10, 2014 (79 FR 7610), we made available a draft guidance entitled “Draft Guidance for Industry; Exempt Infant Formula Production: Current Good Manufacturing Practices (CGMPs), Quality Control Procedures, Conduct of Audits, and Records and Reports” and gave interested parties an opportunity to submit comments by May 12, 2014, for us to consider before beginning work on the final version of the guidance. We received one comment on the draft guidance, but the comment pertained to infant formula ingredients and not to the guidance itself. Consequently, we did not modify the guidance in response to the comment. However, we have modified the final guidance where appropriate to refer to the final rule that was published in the Federal Register on June 10, 2014. The guidance announced in this notice finalizes the draft guidance dated February 2014.

We are issuing this guidance consistent with our good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR part 106 have been approved under OMB control number 0910-0811.

III. Electronic Access

Persons with access to the Internet may obtain the guidance at <http://www.fda.gov/FoodGuidances> or <http://www.regulations.gov>. Use the FDA Web site listed in the previous sentence to find the most current version of the guidance.

Dated: April 8, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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